Commercial Grade Dedication (CGD)
Laboratory-Wide Argonne Procedure LMS-PROC-116, Rev. 3
Effective Date: xx/xx/2015

1 Purpose

Establish the process for the procurement and acceptance of commercial grade items (CGIs) or services that perform a nuclear safety function that were not designed, manufactured, or provided in accordance with the provisions of the American Society for Mechanical Engineers (ASME) NQA-1-2008 Edition, including 2009 Addenda (NQA-1) as an acceptable alternative. These controls provide a reasonable level of assurance that the items or services procured are adequate for their intended safety function.

2 Scope

This procedure applies to the following Argonne activities and entities.

LMS core processes:	Governance
Organizations:	all
Buildings:	all
Specific locations:	Hazard Category 2 or 3 facilities.
Other applicability factors:	When one or more critical characteristics for acceptance cannot be verified by the dedication methods, this procedure cannot be utilized for procurement.
Exclusions:	Items or services from a supplier with an ASME NQA-1 QA Program that has been audited and approved by the Argonne ESQ Quality Assurance Group. Radiological and non-nuclear facilities.

3 Work Process

3.1 Introduction

Commercial grade dedication provides a viable alternative for the use or procurement of items and services that perform a safety function and that have not been manufactured, developed, or performed in accordance with the unique design requirements of the facility or activity or with an ASME NQA-1 Quality Assurance (QA) program required in Argonne Hazard Category 2 (HC2) or 3 (HC3) nuclear facilities. Commercial grade dedication may also be used for items or services approved for use initially at a lower quality level, but that will be used for applications requiring more robust controls (in an HC2 or HC3 facility). The general process includes:

- Confirming that the item or service meets the commercial grade definition criteria
- Technically evaluating an item or service to determine if it performs a safety function identifying the critical characteristics for acceptance
- Selecting, performing, and documenting the dedication methods for determining compliance with the acceptance criteria

3.2 Step-by-Step Procedure

The steps below are mandatory unless noted otherwise.

Step	Job Role	Action
1	Initiator	1.1 Initiate form ANL-746 by completing the information requested in Step 1 of the form. 1.2 Determine if the item or service meets the definition of a commercial grade item and take one of the following actions: • If the item/service meets the definition of commercial grade, proceed to Step 2. • If the item/service does not meet the definition of commercial grade, document the determination in Step 2 of form ANL-746; process ends. **Note:** Exhibit A, Determination of Applicability of the CGD Process, may assist in this determination.
2	Initiator	Perform a technical evaluation and determine the critical characteristics to be used for acceptance of the item or service. See Exhibit B.1 to aid in the technical evaluation.
3	Initiator	Identify critical characteristics for acceptance in Step 3 of form ANL-746. See Exhibit B for an explanation, and Exhibits B.2 and B.3 for examples of critical characteristics.
4	Initiator	4.1 Identify the applicable method of acceptance and document it; this is Step 4 of form ANL-746. See Exhibit C for the selection, performance, and documentation of the approved dedication method(s). They include: 1. Special test(s), inspection(s), and/or analyses (Method 1) 2. Commercial grade survey of the supplier (Method 2) 3. Source verification of the item or service (Method 3) 4. Acceptable supplier/item performance record (Method 4; see note) **Note:** Method 4 cannot be used alone; it must be used in conjunction with Methods 1, 2, and/or 3. 4.2 Forward form ANL-746 to the division quality assurance representative (QAR) for review and approval.
5	QAR	Review form ANL-746 and take one of the following actions: • Disapprove and return to the initiator. Process returns to Step 1. • Approve and forward the form to the design authority.
6	Design authority	Review form ANL-746 and take one of the following actions: • Disapprove and return to the initiator. Process returns to Step 1. • Approve and forward the form to the facility/program manager.

7	Facility/ program manager	Review form ANL-746 and take one of the following actions: • Disapprove and return to the initiator. Process returns to Step 1. • Approve and forward the form to the form to ESQ QA.
8	ESQ-QA	Review form ANL-746 and take one of the following actions: • Disapprove and return to the initiator. Process returns to Step 1. • Approve and forward the form to the initiator.
9	Initiator	Upload approved form ANL-746 to xink using form xink-003.

4 Records Created by Work Process

The records listed below must be retained as indicated.

Description of Record (include form number if applicable)	Custodian	Indexing Method, Storage Medium	Federal Retention Requirement*
Completed form ANL-746 and supporting documentation	Initiator	Manage electronically in xink	Retain indefinitely; DOE currently prohibits destruction (DOE ADM 17.32.a)

*If records are maintained in a business information system that is not currently programmed to purge digital records based on age, the records may be retained in that system past the indicated destruction date.

5 Related Documents

This procedure implements requirements established by the following basis documents.

- U.S. DOE, *Quality Assurance Program Guide,* directive G 414.1-2B.
- U.S. DOE, *Quality Assurance,* directive O 414.1D.

This procedure implements requirements established by the following Argonne policies and procedures.

- *Applying the Graded Approach for Quality,* LMS-PROC-125.

The following documents provide background information relevant to the subject of this procedure.

- ASME NQA-1-2008 Edition, including 2009 Addenda, *Quality Assurance Requirements for Nuclear Facility Applications*. Available through the Argonne Research Library.
- EPRI TR-102260 Project Q101-43, Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items.
- U.S. DOE Office of Environmental Safety and Quality, *Guidance for Commercial Grade Dedication*.
- U.S. DOE, *Integrated Safety Management System Guide*, directive G 450.4-1B.

6 Definitions

The following definitions can be found in the Argonne Policy and Procedure Dictionary and are applicable to this procedure.

commercial grade item (CGI)

commercial grade service (CGS)

commercial grade survey

critical characteristics

dedication

design authority

equivalency evaluation

equivalent replacement

important to safety

like-for-like replacement

reasonable assurance

safety class structures, systems and components (safety class SSC)

safety function

safety significant structures, systems and components (safety significant SSC)

safety structures, systems, and components (safety SSC)

technical evaluation

vital safety systems (VSS)

7 About this Procedure

Issuing LMS core process:	Governance
Issuing organization:	Office of the Laboratory Director
Final approver:	Paul K. Kearns
Point of contact:	Steven A. Gauthier
Review cycle (months):	24 months
Date last revised:	xx/xx/xxxx
Date last reviewed:	xx/xx/xxxx

8 Summary of Changes in This Version

Revision 3 differs from Revision 2 as follows: Added critical characteristics for computer software to Exhibit B; changed flow of procedure and additional editorial corrections throughout. Removed reference to LMS-PROC-48, *Requesting Supplier Evaluation.*

Exhibit A: Determination of Applicability of the CGD Process

A facility procuring an item or service that supports a nuclear safety function has two options to procure the item or service. The item or service must be either procured or performed subject to the requirements of ASME NQA-1 (Parts I and II) or be commercially grade dedicated in accordance with ASME NQA-1 (e.g., ASME NQA-1-2008, Part I, Requirement 7, Control of Purchased Items and Services; NQA-1-2008, Part II, Subpart 2.14 Quality Assurance Requirements for Commercial Grade Items and Services).

U.S. DOE Office of Environmental Safety and Quality, Guidance for Commercial Grade Dedication, September 2011, is a guide that provides amplified guidance in addition to requirements defined by this procedure. The guide states that it is the expectation of senior DOE EM management that the guide should be implemented for commercial grade dedication (CGD).

A.1 Acquisition of New Products

Acquisition of a product or service may be limited by cost or the availability of a product if a supplier is unable to produce the product with all the quality controls and documentation required by the designated quality level of the intended end use. When commercially available products or services can be demonstrated to have operational and product design characteristics that meet the performance requirements, then this procedure is used to allow dedication of the product or service for a specific application at a higher or equivalent quality level than the level at which the product was acquired. To be applicable, the product or service must meet the definition of a commercial grade item (CGI). Standard procurement practices must be followed to acquire the product.

A.2 Use of In-house Products

Facilities, experimenters, and design organizations may find products that appear to meet product requirements from surplus material sources, warehoused items, other DOE laboratories, sponsor or facility user-supplied items, etc. Use of this procedure is required to determine whether such products are acceptable because of their unknown use and storage histories. Even if the product manufacturer identity and product catalog information are attainable, it is likely that it will be impossible or cost prohibitive to determine what the status of the quality system was or its applicability to the product at the time it was produced.

A.3 Services

Services may be considered too costly or affect the schedule too dramatically to acquire from a specialized provider who does not have an in-place quality assurance (QA) program that meets Argonne requirements. In these situations, the overall project needs may be met by Argonne oversight, technical reviews/approval of the service provider's processes, inspection, and other additional controls.

A.4 Like-For-Like Replacement

The responsible design authority determines whether a CGI is a "like-for-like replacement" item for the original. Like-for-like replacement items are often spare parts procured at the same time and under the same controls as the original. A like-for-like replacement must meet all the following criteria:

- The replacement item was purchased at the same time, from the same vendor, and under the same controls as the item it is replacing or the user can verify that no changes have been made in the design, materials, or manufacturing process since procurement of the item being replaced.
- The replacement item carries the same published product description.
- Performance of the CGI supplier has been satisfactory.

- The replacement item has been maintained in an appropriate controlled condition.

Note: Hazard Category (HC) 2 and HC3 nuclear facilities may require subjecting the proposed "like-for-like" installation to their USQ process (Approved Equivalent Part Procedure).

Reliance on verification of the part number and other identification characteristics alone is insufficient to guarantee the quality of commercially procured products because of the possibility of undocumented changes in the design, material, or fabrication of CGIs with the same part number.

If differences from the original item are identified in the replacement item, the item is not identical (not like-for-like) but similar to the item being replaced. An equivalency evaluation is necessary to determine whether any changes in design, material, or manufacturing process could have an impact on the functional characteristics of the safety structure, system, or component (SSC) and ultimately on its ability to perform its required safety function. Items that have been in storage must be inspected for evidence of deterioration or damage, remaining shelf life, if applicable, and evidence of suspect/counterfeit items (S/CI). When items are installed in operating systems, it must be determined if successful installation and/or operational functionality is required as the last item in determining the item's acceptability for service.

When a new item is acquired from the vendor (identical catalog part) and it has been determined that no changes have been made in the design, materials, or manufacturing process since procurement of the item being replaced, normal procurement processes (including any necessary CGD processes for critical parameter verification) can be used to make the purchase.

Exhibit B: Critical Characteristics Used to Determine that a Product, Service, or Process (CGI) Is Acceptable for a Given Application

Commercial grade dedication is used to determine whether the condition of a product or service (considering probability and consequence) represents an unacceptable risk. Critical attributes to consider include functionality, requirements of applicable standards, and design requirements.

B.1 CGI Technical Evaluation

The design authority must determine the functional requirements and the corresponding critical characteristics of an item necessary for determining that functional/technical requirements are met. Only items or services that perform a safety function shall be considered candidates for dedication. Consideration must be given to the following:

- If the item is to be used in a nuclear facility or other facility covered by a documented safety analysis, then the stipulated process requirements (such as unreviewed safety questions (USQs); approved equivalent part determination; additional evaluations or approvals; and/or the need to revise design, operating, or safety basis documentation) must be followed as stipulated for that facility.
- If applicable, identify the Critical Characteristics for Design.
- If applicable, select the Critical Characteristics for Acceptance.
- Identify any safety class or safety significant functions of the item, regardless of whether the item is covered in a documented safety basis.
- Select identifiable and measurable attributes or variables appropriate for the safety function.
- Items listed in a design output document that are commercially produced must require a technical evaluation to determine whether they perform a safety function.
- Other aspects “important to safety” may need to be considered for the particular use of the CGI.
- Services should be evaluated to determine their individual safety function in relation to the component or equipment.
- Identify whether a failure of the item could have a safety impact that could cause injury or damage beyond the functional requirements.
- Identify whether the use of a nonconforming item or whether failure in service of the item can cause unacceptable program costs or delays.
- Determine requirements mandated by applicable codes and standards, regulations, and rules, or Argonne commitments.
- Determine the item’s functional performance.
- Credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function; use of failure mode effects analysis (FMEA) may be helpful in determining required product/service attributes, technical evaluation, and selection of critical characteristics.

Identify what must be known about the item to accept it for use in the specific application. Identify the following:

- Critical characteristics of the item necessary to provide the required functional capability and/or to meet any other requirements for the application;
- Replacement items, which should be evaluated to determine their individual safety function in relation to the component or equipment;
- Determine whether the replacement item is a like-for-like or equivalent item;
- Criteria related to the location of the item in the facility or criteria addressing the most severe location of the item in the facility, unless controls are in place to prevent usage in undesignated locations;
- The supporting documentation a supplier provides on the item, to include, but not be limited to: part number, physical characteristics, identification markings, and performance characteristics. Additional information can include such information as physical/chemical test reports, ISO certification, etc.;
- Any personnel qualification requirements and activity controls, particularly for a service;
- If an item is already at Argonne, determine whether there are any documents, traceable to the item, that provide acquisition, storage, or use history;
- In cases where the critical characteristics cannot be determined from any existing documentation (e.g., manufacturer's documentation), an engineering evaluation, examination, and/or test may be performed to develop the appropriate critical characteristics and acceptance criteria;
- CGIs designated for installation in seismically or environmentally qualified equipment or in locations that require such qualification will include identification of applicable critical characteristics to ensure that the original qualification of the component or equipment is maintained and that the item will perform its intended safety function in the designated location.

B.2 Typical Critical Characteristics (for non-software items/services)

These typical characteristics (lists may not be considered all-inclusive) may be critical for a given product and the use application. Refer to DOE Guidance for Commercial Grade Dedication for additional characteristics. Any combination (one or more) of Methods 1, 2, or 3 can be used to verify conformance of these items.

The identification of the critical characteristics to be verified for acceptance is a design activity that is based on the complexity, application, function, and performance of the item or service for its intended safety function. This identification can include methods to link items with the manufacturer's product description and published data (e.g., part or catalog numbers, identification markings). The dedication process must not rely on the part number alone as the only critical characteristic to be verified for acceptance. Critical characteristics for service can include personnel qualification and activity controls.

Product Identification	
Color coding	Nameplate data
Display type (scale, graduations)	Enclosure type
Industry standard markings	Part number/unique identifier
Performance Characteristics	
Accuracy	Load rating
Burn-in endurance	Magnetic properties

Calibration to required accuracy/range of interest	Open/closure time
Calibration maintained over specified time period	Operability (fail open/close, stroke)
Chatter	Operating range
Current rating	Performance test outcomes
Cycle time	Pick-up/drop-out voltage
Dead band width	Power rating
Flow rate	Pressure drop
Gain performance during under voltage conditions	Pressure rating
Horsepower	Ride out
Input/output voltage	Rotational direction
Interrupt rating	Set point stability (no drift)
Interrupting current	Speed
Leakage	Time/current response
Life expectancy (age, operating hours, etc.)	Validation and verification software
Physical Characteristics	
Balance	Inductance
Capacitance	Luminescence
Cloud point	Material of construction
Coating	Notch toughness
Color oil/water separation	Viscosity
Composite material hardness	Permeability
Concentration	Plating
Conductivity	Polarity
Continuity	Pour point
Density/specific gravity	Purity
Dielectric strength	Resilience
Dimensions (to within manufacturer's tolerance)	Resistance
Drop point	Solubility
Ductility	Spring constant
Code or standard version used in manufacturing	Standards used in joining (American Welding Society [AWS], ASME, etc.)
Durometer hardness	Surface finish
Elasticity	Surface hardness
Fatigue strength	Suspect/counterfeit item (verify validity of product)
Flammability	Tensile strength
Flashpoint	Torque
General configuration or shape	Total chloride content
Heat treatment	Weight
Homogeneity	

B.3 Typical Critical Characteristics for Software Items/Services

Any combination (one or more) of Methods 1, 2, or 3 can be used to verify conformance of the items detailed in Tables B.1 through B.4. (Exhibit C includes descriptions of Methods 1 through 4.)

Table B.1 Item Characteristics

Critical Characteristic	Description	Acceptance Criteria	Method of Verification
Host computer operating environment	The manufacturer and model number of the host assembly or computer hardware where the computer program is intended to reside. This critical characteristic is applicable to all computer programs.	Host computer operating environment criteria must match the purchase specification. This criteria should include the manufacturer name and model from a supplier's catalog (e.g., Dell PowerEdge T110 Tower Server, IBM AIX & System, Dell Precision T3500 Workstation, Siemens Simatic S7-400).	Verified through one or more of the following: • Inspection of receipt inspection documentation (Method 1). • Inspection of test system operating system identifiers (Method 1).
Host computer operating system identifier	Vendor name, operating system version, service packs or patch identifiers that are needed for the computer program to be executed. This critical characteristic is applicable to all computer programs.	Host computer operating system identifier must match the identifier in the vendor product list (e.g., Microsoft Windows 7, UNIX Operating System Version 5.1, B-5, and Yokogawa Pro-Safe-RS R2.01.00).	Verified through one or more of the following: • Inspection of receipt inspection documentation (Method 1). • Inspection of test system operating system identifiers (Method 1).
Name of computer program	The full name of the computer program. It should be the same identifier as used during the procurement/ acquisition process. This critical characteristic is applicable to all computer programs.	Computer program's name must match the product name from vendor catalog (e.g., CFAST, Wolfram Mathematica 8, Monte Carlo N-Particle Transport Code System [MCNP5], Emerson Valve Link, and Organic Concatenater).	Verified through one or more of the following: • Inspection of receipt inspection documentation (Method 1). • Inspection of test system operating system identifiers (Method 1).
Version identifier of computer program	The complete version identifier, including any patches. This critical characteristic is applicable to all computer programs.	Computer program's version identifier must match the product identifier from the vendor catalog that includes the computer program's name; major functional version; minor functional version; corrective revision (e.g., CFAST-05.00.01, Hotspot-2.07.01, Emerson Valve Link-02.04-13, and Organic Concatenater-3.1b).	Verified through one or more of the following: • Inspection of receipt inspection documentation (Method 1). • Inspection of test system operating system identifiers (Method 1).
Name(s) and	The complete name,	Support tool name and	Verified through one or

identifier(s) of support tools	including version identifier of all support tools that are used during the CGD process to assist in performing special tests or other support tools used in the operations environment. These tools, such as PLC test simulator tools and database management systems, could affect the correct operation of the safety functions performed by the computer program during special tests or operations.	identifier must match the product identifier from the vendor catalog or specification.	more of the following: • Inspection of receipt inspection documentation (Method 1). • Inspection of test system operating system identifiers (Method 1).

Table B.2 Physical Critical Characteristics

Critical Characteristic	Description	Acceptance Criteria	Method of Verification
Interfaces: User interface (UI)	The computer program user interface design that provides consistency in design, including use of symbols, notations, terminology, conventions, and layout that are important to the safety function. Although applicable to all computer programs, this critical characteristic may be more important for computer programs that have multiple users, are used in control rooms, or used by safety component maintenance staff.	User interface can be expressed by how well the user interface that is related to the safety function meets company interface designs (e.g., 100% of UI meets Americans with Disability Act requirements).	Verified through: Review of computer program inspection reports as compared to industry interface standards (Method 1).
Receipt media	The physical object or distribution media received from the supplier that contains the computer program. This critical characteristic is applicable to all computer programs.	Receipt media criteria are expressed as the method in which the computer program is distributed to the dedicating entity (e.g., CD, embedded, and downloadable).	Verified through: Inspection of media (Method 1).

Size (lines of code, function points)	The size of the computer program. This critical characteristic can be the quantity of folders received, the size in Kb of the executable(s), number of function points, or other physical means of measuring the size of the computer program. This critical characteristic can be important for embedded computer programs that must operate in processors with limited memory or storage or stand-alone computer programs that must execute with limited memory or storage.	Size criteria can be expressed in terms of several different methods of measurement (e.g., 500K source lines of code [SLOC]), number of data functions, and number of transactional functions).	Verified through one or more of the following: • Review of design documentation (Method 2). • Execution of support tools that measure size (e.g., function points) (Method 1).

Table B.3 Performance Critical Characteristics

Critical Characteristic	Description	Acceptance Criteria	Method of Verification
Abnormal behavior: Response to abnormal conditions and events	Action or behavior that the computer program detects and to which it responds, including invalid inputs, erroneous states, and abnormal conditions. This critical characteristic is important to identifying a risk that the computer program will fail to execute its safety functions.	As described in computer program requirements or procurement specification documentation. The criteria can be expressed as actions to the operations console when a warning event occurs (e.g., alarm on low power signal, entry of erroneous data input, entry of erroneous data sets, or initiation of data backups).	Verified through a combination of one or more: • Inspection and testing (Method 1). • Review of design (Method 2). • Observation of development (Method 3). • Review of the installed base to determine performance history (Method 4).
Accuracy/precision/ tolerance outputs	For accuracy, the degree to which there is a close correlation with the expected or desired outcome. For precision, the degree of repeatability or degree of measure. For tolerance, the allowable possible error in measurement.	As described in computer program requirements or vendor specification documentation. Criteria may be: accuracy, +/− 1%; precision, +/− 0.0001; tolerance, +/− 0.00001.	Verified through a combination of one or more: • Observation and review of design (Method 3). • Inspection and testing (Method 1). • Review the installed base to determine performance history (Method 4).

Environmental compatibility: Portability	The measure of the effort required to migrate the computer program to a different hardware platform, component or environment. This critical characteristic may only be important for computer programs that are expected to be executed in a different environment.	As described in computer program requirements or vendor specification documentation. Portability criteria can be expressed as a unit of time (e.g., 16 hours or 15 days).	Verified through: Performing migration to one or more environments equivalent to the dedicating entities (Method 1).
Functionality: Completeness	The measure of the extent that the computer program design and implementation have satisfied the allocated safety requirements. This critical characteristic is important to identifying risks that the computer program will fail to execute its safety functions.	Functionality completeness is based upon how many of the computer program's requirements have been verified to be successfully implemented. Functional completeness can be expressed as a percentage of requirements implemented (e.g., 100% of allocated safety requirements are met).	Verified through a one of the following: • Performing a review of the functional requirements' traceability to test cases, and • Verification that those test cases were successfully executed (Method 2). If requirements traceability is unavailable, the dedicating entity can develop the traceability matrix from the computer program's requirements or procurement specifications and test cases performed (Method 2).
Functionality: Consistency with appropriate engineering/scientific research and professional technical approaches	Degree to which the computer program's sample or complete data sets of results correlate with experimental data, expected data results, or professional analyses and degree to which any erroneous data sets do not correlate with the experimental data or professional analyses. This characteristic is most likely critical to computer programs used to perform analysis of accident and structural integrity analyses for determining proper design of safety components.	Consistency with appropriate engineering/ scientific research and professional technical approaches is based on peer-reviewed, published technical papers or industry-accepted computer programs performing a similar function. The output of the computer program can be viewed as how closely the computer program's output matches the technical report or baseline computer program output (e.g., computer program output correlates with experimental data to +/− 3σ.)	Verified through a combination of one or more: • A comparison of detailed results in a peer-reviewed technical publication against the computer program's output for a similar problem being solved (Method 1). • A comparison of the baseline computer output to the computer program's output that is being dedicated. The baseline computer program must solve the same or a closely similar physical problem as that of the dedicating computer program (Method 1).

			• A review of the computer program's current user base and its applicability to the intended use by the dedicating entity (Method 4).
Functionality: Correctness (correctness, proof of correctness)	The degree to which the computer program is free from errors, meets the specified requirements, and meets the user's needs. Correctness differs from completeness in that the number of requirements implemented is not considered. Formal techniques may be used to mathematically prove that the computer program satisfies its specified requirements. This critical characteristic is important to identifying risks that the computer program will fail to execute its safety functions.	Correctness may be expressed as how well the computer program satisfies its requirements. The number of errors identified for each requirement can be an indicator as to the correctness. The severity or impact on performing the safety function correctly should be a factor in determining correctness (e.g., 0 major errors reported, 5 minor errors reported, and 3 minor errors repaired and being tested).	Verified through: Review of the test results error categorization (Method 2).
Functionality: Security functions	The protections included in the computer program and operating environment which provide access to authorized users or which eliminate or mitigate unwanted access or unintended modification or the computer program. This critical characteristic may be important for computer programs that are executed on computer networks that are used by multiple individuals or are susceptible to intrusions.	As described in computer program requirements, procurement specification documentation, and/or compliance standards. The criteria can be expressed as the presence of strong passwords, or biometric access, and network design including firewalls.	Verified through a combination of one or more: • Inspection and testing (Method 1). • Observation and review of design (Method 3). • Review of the installed base to determine performance history (Method 4).
Functionality: Interface communications (usability,	The measure to which the computer program operates properly and shares resources with	Interface communication may be expressed as how the computer program uses standardized or industry	Verified through one or more of the following: • Observation of computer program execution to

interoperability, communicativeness)	other computer program or hardware operating in the same environment; the ease with which the various components of the system communicate with each other and external entities and to which the complexity of the interfaces is minimized. This critical characteristic may be important to stand-alone computer programs that are part of a complex analysis or component design and for many operator-controlled devices such as digital cranes.	approaches in its design and implementation. These interfaces identify how well the computer program accepts input from or can send output to other systems (e.g., number of manual process steps needed to transfer the computer program output to be used as input to another computer program) and uses industry and accepted port assignments (e.g., controller output port 3 is used to communicate with operator console) and the ease with which operator controls are received by the computer program (e.g., all operator controls are via haptic devices such as joysticks).	assure interface standards are met (Method 3). • Review of computer network design drawings (Method 3). • Execution or observation of tests that exercise the external interfaces (Method 1). • Inspection of the user manual content that describes the process to receive or send electronic information to or from the computer program (Method 1).
Functionality: Specific safety functions and algorithms	The critical functions or calculations that are performed. This critical characteristic includes time-dependent functions and is important to verify for all computer programs being dedicated.	As described in computer program requirements or procurement specification documentation. Functionality criteria may be similar to: a given detector signal, close valve or given source input data, a calculated dose exposure at 10 meters and 0 receptor height.	Verified through a combination of one or more: • Inspection and testing (Method 1). • Observation and review of design (Method 3). • Review of the installed base to determine performance history (Method 4).
Interfaces: Critical input parameters and valid ranges	The set of input parameters that are used in the critical functions of the computer program and the range of their valid values. This critical characteristic is important to all types of computer programs to ensure that the computer program will function properly for all possible operational inputs.	As described in computer program requirements or procurement specification documentation. This criteria may be input voltage (e.g., 1.5 to 2.8 ohms), deposition receptor height (e.g. 0 to 1 ft), time: (e.g., dd/mm/yyyy, hh:mm:ss); and length (1.00 to 5.00 meters).	Verified through a combination of one or more: • Inspection and testing (Method 1). • Observation and review of design and/or implementation (Method 3). • Inspection of user's manual (Method 1). • Review of the installed base to determine performance history (Method 4).
Interfaces: Outputs parameters	The characteristics of the critical output parameters include file formats, signal specification,	As described in computer program requirements or procurement specification documentation. This criteria can be specification of	Verified through a combination of one or more of the following: • Inspection and testing (Method 1).

	mathematical notations type, signal strength, and signal type. This critical characteristic is important to all types of computer programs to ensure that the computer program output is in the expected format or units of measure.	output filename (e.g., 28 characters, case insensitive with a file extension of pdf), output format specification (e.g., comma delimited), and units of measure (e.g., ohms, 1.0E-24, barns).	• Inspection of user's manual (Method 1). • Observation and review of design (Method 3). • Review of the installed base to determine performance history (Method 4).
Response Time	The time it takes the computer program to execute a specific action. This critical characteristic may be important to digital equipment that must perform an action within a specific period of time. Rarely is response time important to stand-alone computer program applications.	Response times can be expressed in terms of time in days, minutes, seconds or milliseconds (e.g., the alarm is reported to the console 3 seconds after detection and calculation results are completed within 20 minutes).	Verified through: Observation or execution of a functional test that is timed (Method 1).
Throughput	The measure of the amount of work performed by a computer program system over a period of time. This critical characteristic would rarely be important for digital equipment that performs on-demand safety functions. This critical characteristic may be of best use for large analytical computer programs that require several hours to perform calculations.	Throughput can be expressed in terms of completing a specified quantity of an object over a period of time (e.g., number of millions of instructions per second, and number of bits per second).	Verified through: Observation or execution of functional test that is timed (Method 1).
Reliability	Extent to which the computer program can perform its critical functions without failure for a specified period of time under specified conditions. This critical characteristic is more likely to be important for dedication of digital equipment. Can be used for stand-alone computer	Reliability is typically expressed in terms of number of failures over a period of time (e.g., 1 failure per year in a high radiation environment) or number of failures for any given number of executions of the computer program (e.g., 3 failures for every 100 computer runs).	Verified through: Observation or execution of a functional test that is timed or otherwise uses a counting attribute (Method 1).

	programs used in design or analyses.		

Table B.4 Dependability

Critical Characteristic	Description	Acceptance Criteria	Method of Verification
Built-in quality: Existence of QA program	A QA program that includes documented procedures or process controls. A QA program generally complies with a recognized standard (e.g., ISO 9000, ASME NQA-1). This critical characteristic can be used to determine whether the foundation of a QA program exists.	QA program criteria are based upon the vendor's procedural compliance to a recognized standard that addresses development and quality assurance for computer programs. This criteria can be expressed in terms of the number of significant findings from a compliance audit as measured against the chosen recognized standard, or achievement of certification for the chosen recognized standard (e.g., ISO 9001).	Verified through one or more of the following: • Inspection of evidence of any third party certification (ISO Certification) (Method 1). • Review of audit reports (Method 2). • A survey to measure performance as compared to the chosen recognized standard (Method 2).
Built-in quality: Training, knowledge, and proficiency of personnel performing the work	Staff training, knowledge, and proficiency associated with the design, development, testing, and oversight of the computer program; experience in similar projects; and familiarity with specific tools and languages used in the design and implementation. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Staff training, knowledge, and proficiency criteria may include how well the specific staff member satisfies the vendor's qualification requirements for the position held. The criteria can be the percentage of qualification requirements met.	Verified through: Review of objective evidence of attendance at courses, staff resumes, and on-the-job training as compared to the vendor qualification requirements to determine how well the staff member satisfies the requirements (Method 2).
Built-in quality: Adherence to coding practices	Degree to which the computer program complies with approved coding standards, use of code libraries, or automated configuration management tool. This critical characteristic can be used to provide an indicator of remaining errors in the program.	Coding practice criteria can be a percentage (e.g., 90%) of the vendor coding standards met and (where appropriate) 100% of possible code library modules are used instead of recoding.	Verified through: Review of code inspection reports or other vendor evidence, including reviews of coding practice for the subject code modules. The dedicating entity during a survey may also review compliance of the code module with the vendor's documented practices (Method 2).
Built-in quality:	The measure in which	Code structure criteria can	Verified through:

Code structure (complexity, conciseness)	the computer program is legible, complexity is minimized, and code length is minimized. This critical characteristic can be used to provide an indicator as to the difficulty to verify through reviews and testing that the code will perform as expected.	be quantitative through the use of static analysis tools or qualitative through reviews of the documented design or inspection of the code. Code structure criteria may take the form of the number of internal subroutine interfaces, number of do-loops, numbers of exits from a module, straightforward flow of logic in code module, and code module depth and breath.	Review of the vendor-documented evidence from the use of a static analysis tool or performance by the dedicating entity of an inspection and manual analysis of the documented design or computer program code (Method 2).
Built-in quality: Error minimization (defect density, defect containment effectiveness, defect severity)	The degree to which errors are minimized. Indicators include defect density, effectiveness of error detection techniques to keep errors from entering the next software lifecycle phase, and severity of the errors detected. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Error minimization criteria can include quantitative and qualitative measures. The acceptance criteria selected should be appropriate for the computer language or code generation tool used to create the computer code. Error minimization criteria may be the number of errors detected per lines of code (e.g., 5 errors per 100 lines of code), number of errors per pre- and post- release (5 major and 10 minor errors), and number of errors per software lifecycle phase (7 errors in requirements phase).	Verified through: Review of vendor-tracked errors detected during reviews and inspections during the development and testing of the computer program. Through inspection of the vendor's documented reviews, the dedicating entity may develop the values associated with the acceptance criteria (Method 2 or 3).
Built-in quality: Internal reviews and verifications	The degree to which static analysis methods (e.g., peer reviews) are performed during the computer program's development to identify errors and non-compliance to vendor procedures and standards.	Criteria for internal reviews and verifications effectiveness is based upon the ratio of errors identified during the review/verification and the number of errors that are discovered in the next lifecycle phase (e.g., ratio of the number of requirements errors identified during requirements review and the number of errors detected during the design phase).	Verified through: Inspection and analysis of results from reviews or verification activities performed in two or more adjacent life cycle phases (Method 2 and/or Method 3).

Built-in quality: Maintainability	The computer program design that provides for ease in performing modifications to the computer program. This critical characteristic may be more appropriate for computer programs whose failure could result in few or no alternatives should the computer program be unusable.	Maintainability criteria are based upon the time required to change the computer program. This criterion can be expressed as mean time to change or mean time to fix.	Verification through: Review of vendor metrics associated with the length of time to evaluate the change/error correction, make the code change/correction, test the change/correction, update all computer program documentation, and release the change (Method 2).
Built-in quality: Process effectiveness	A measure of how well the vendor's QA process meets its purpose and objectives. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Process effectiveness criteria are based upon the degree to which third party certification/recertification programs are achieved (e.g., 90% of achievement of compliance to Capability Maturity Model Integration (CMMI) Software Engineering Institute (SEI) maturity level 4 or achieved ISO 9001) or by qualitative measures of conformance to the vendor procedures (e.g., 75% of vendor computer program procedures are met).	Verified through one or more of the following: • Inspection of the proof of third party certification (ISO 9001 Certification) (Method 1). • Review of vendor procedures and objective evidence that processes performed to produce the computer program is compliant with those procedures (Method 2).
Built-in quality: Testability	The measure of the effort required to perform computer program verification, validation, and installation testing. This critical characteristic may be appropriate to use when assurance is needed that reviews and tests were adequately performed.	Testability criteria are based on the ease or difficulty in conducting verification and validation activities. Testability criteria may include: number of hours to perform peer reviews, number of hours to pretest a module, and number of hours to develop test cases.	Verified through: Inspection of documented review reports and test records that include the time spent to prepare, conduct, and perform post review or test activities (Method 1).
Built-in quality: Thoroughness of computer program testing	A measure of the completeness of the computer program testing to ensure that the computer program is correct and complete. This critical characteristic may be appropriate to use for ensuring that tests were	Thoroughness of computer program testing criteria can be measures that identify the quantity of errors discovered during the various testing activities (e.g., trend analysis of errors per module, comparison of pre- and post-release errors) and	Verified through: Review of the objective evidence of the errors identified during the testing processes or traceability of safety requirements to tests completed. If objective evidence is not available, the dedicating entity may be able to create the

	adequate to provide the reasonable assurance that the safety functions can be performed satisfactorily.	traceability of tests performed to the safety requirements for the computer program (e.g., 95% of the requirements were tested).	traceability of the safety requirements to tests performed from the computer program's documented requirements and test reports (Method 2).
Configuration control: Control of enhancements	The computer program improvements are controlled, approved, and necessary. Requirements churn is minimized but not zero. Control of enhancements minimizes unintended or prohibited functions. This critical characteristic may be appropriate to use when the stability of the computer program is important. This critical characteristic can provide an indicator as to the number of errors inserted into the computer program during the change process.	Control of enhancements criteria can be obtained from configuration control board statistics. These statistics may include number of enhancements (e.g., 15 changes/last year), number of approved enhancements (e.g., 7 changes/last year), and number of completed enhancements (e.g., 3 changes/last year).	Verified through: Review of meeting minutes of a configuration control board, data from change logs, and release notes (Method 2).
Failure management: Isolation of safety functions	The computer program design implements methods of cohesion, reduces coupling, and promotes modularity. Cohesion is a module or routine that performs a single task or function. Modularity or decoupling is a module or routine that performs an independent task or function. Nominally, this measure is qualitative. This critical characteristic provides an indicator to determine how much of the non-safety portions of the computer program must be included in the CGD process to provide the reasonable assurance that the failure of non-safety functions will not	Isolation of safety functions criteria can be the total number of computer program modules that perform safety and non-safety functions; there is no sharing of logic between safety and non-safety modules, and non-safety modules or routines may only read output of safety modules or routines.	Verified through: Review of the computer program design or source code (Method 2).

	affect the proper execution of the safety functions.		
Failure management: Redundancy	The computer program design to implement duplication of critical components with the intention of increasing reliability. This critical characteristic may be important when the failure of the safety function can lead to severe consequences that harm individuals or the environment. This critical characteristic may be more applicable to a computer program that controls instrumentation.	Redundancy criteria may include the existence of back-up critical hardware computing systems, multiple computer program development teams, information redundancy, multiple controllers, and dual processors.	Verified through: Review of the computer program design, computer processor specifications, and computer system drawings (Method 2).
Problem reporting: Notification to customers	Notification by the vendor to customers of potential computer program errors or weaknesses.	Criteria for notification to customers may be the presence and use of a problem-reporting system, use of problem-reporting metrics, and number of notifications to the users over time.	Verified through: Criteria verification for notification to customers is performed by reviewing (1) communications of errors with users, (2) any Web site or other form of communicating with the vendor, and a log of communications (Method 2).
Supportability	The ability for the vendor to continue support for the computer program over the life of its use. This critical characteristic is important because of the difficulty of ensuring that the computer program is free of all errors. This critical characteristic should be considered when alternative computer programs are not easily obtained or where financially infeasible.	Supportability criteria can be the stability of the vendor based upon the longevity of the business (e.g., 20 years in business), size of customer base (e.g., 1,000 customers worldwide), planned future product releases (e.g., vendor R&D has updates scheduled for next 3 years), and vendor history of discontinuing products (e.g., cancelled 3 product lines over past 2 years).	Verified through: Review of the vendor history for the specific computer program, as well as the vendor's history in supporting similar computer programs or products (Method 4).

Built-In quality: Conformance to national codes and standards	The computer program's compliance to applicable national codes and standards.	Conformance criteria can be a measure of how well the computer program meets industry-accepted practices that provide a qualitative pedigree of the computer program.	Verified through one of the following: • Inspection of vendor-performed assessments of the computer program as compared to the national code or standard (Method 1). • Review of computer program documentation and artifacts as compared to the selected national code or standard (Method 2).

Exhibit C: CGI Determination Methods

The commercial grade item or service must meet the acceptance criteria for the identified critical characteristics by inspection, tests, or analyses performed after delivery, supplemented as necessary by one or more of the following methods. The selection of dedication method(s) is based on the type of critical characteristics to be verified for acceptance, available supplier information, quality history, and degree of standardization. Supplemental dedication methods will be planned and completed prior to delivery of the CGI or performance of the service.

C.1 Methods

Method 1: Special Tests, Inspections, and/or Analyses

Special tests, inspections, or analyses can be conducted upon or after receipt of an item to verify conformance with the acceptance criteria associated with the identified critical characteristics. This effort may include post-installation testing, using a sampling plan, when appropriate. CGI inspection is performed in accordance with LMS-PROC-49, *Receipt Inspection*, and/or ESQ-QA-8.1, *Source Verification*.

When post-installation testing is used to verify acceptance criteria for the critical characteristics, the commercial grade item or service must be identified and controlled to preclude inadvertent use prior to completion of the dedication activities.

Special inspections include receipt inspection activities to verify that criteria associated with procurement activities are adequate.

Method 2: Commercial Grade Survey of the Supplier in accordance with ESQ-QA-8.2, *Commercial Grade Survey*

A commercial grade survey is completed using a commercial grade survey checklist (Form ANL-746) that identifies the critical characteristics for acceptance, including:

- Identification of the item(s), or product line, or service included within the scope of the survey
- Identification of the critical characteristics to be controlled by the supplier
- Verification that the supplier's processes and quality program controls are effectively implemented for control of the critical characteristics
- Documentation of the adequacy of the supplier's processes and controls

For suppliers found to have acceptable processes and controls associated with the defined critical characteristics, the implementation of these controls must be specified as a condition of their procurement with Argonne. Furthermore, the associated CGI must be accompanied by a Certificate of Conformance provided by the supplier, attesting to the implementation of the identified processes and controls. The commercial grade survey documentation will provide objective evidence that the processes and controls required for the identified critical characteristics were observed and evaluated for acceptance. Exhibit E provides additional requirements related to Certificates of Conformance.

Surveys performed by other organizations may be used as a supplemental basis for acceptance, if the identified critical characteristics, survey scope, and the supplier's processes and controls are consistent with the dedication and acceptance criteria determined by Argonne and accepted by ESQ-Quality Assurance.

Commercial grade surveys will be conducted at sufficient frequency to determine that process controls applicable to the critical characteristics of the item or service procured continue to be effectively implemented. This determination will be made on a case-by-case basis, taking into account intended use at Argonne, historical performance, changes in supplier ownership, and credible industry-based information. The frequency interval of surveys will not exceed the interval used for supplier audits.

A commercial grade survey may not be used as a viable method for suppliers with undocumented quality programs or with programs that do not effectively implement the supplier's own specified processes and controls.

NOTE: Commercial grade surveys may not be used as a basis for accepting items from distributors unless the survey includes the manufacturer and the survey confirms adequate processes and controls by both the distributor and the manufacturer. A survey of the distributor may not be necessary if the distributor acts only as a broker and does not warehouse or repackage the items, or if traceability can be established by other means (e.g., verification of the manufacturer's markings or shipping records).

Method 3: Source Verification of the Item or Service in accordance with ESQ-QA-8.1, *Source Verification*

Source verification may be conducted at the supplier's facility or at Argonne after receipt for the actual CGIs. Source verification will verify acceptable results of inspections, examinations, or tests at predetermined points. The scope of source verification may include witnessing fabrication and assembly processes, nondestructive examinations (NDEs), performance tests, final inspections, design, procurement, calibration, and/or material process control methods relevant to the CGI. Documentation of source verification will include:

- Identification of the items or services included within the scope of the source verification
- Identification of the critical characteristics, including acceptance criteria, to be controlled by the supplier
- Verification that the supplier's processes and controls are effectively implemented for the identified critical characteristics
- Identification of the activities witnessed during the source verification and the results obtained
- Documentation of the adequacy of the supplier's processes and controls

Method 4: Acceptable Supplier/Item/Service Performance Record

Supplier/item performance records may be used as a method to dedicate CGIs for identical or similar applicable services if the performance records provide reasonable assurance that the identified critical characteristics are acceptable.

Note: Method 4 cannot be used alone as an acceptance method and must be used in conjunction with Methods 1, 2, and/or 3. Furthermore, Method 4 cannot be used if the only history available is with the purchaser (acceptable history must be demonstrated from independent sources, e.g., other DOE Laboratories).

To meet requirements for this method, performance records will include the following:

- Identification of the supplier/item/service being evaluated
- Identification of previously established critical characteristics specific to the supplier/item/service
- Identification of industry data examined to evaluate the supplier/item/service
- Identification of basis for determining that industry data substantiates acceptability of the supplier/item/service

- Documentation of the adequacy and acceptance of the supplier/item/service performance record
- Condition of service, environmental condition, failure data, maintenance, testing, and any modifications

An acceptable supplier/item/service performance record will not be used unless:

- The established historical record is based on industry-wide performance data that are directly applicable to the critical characteristics and the intended facility application (a single source of information is not adequate to demonstrate satisfactory performance)
- The manufacturer/supplier's measures for the control of applicable design, process, and material change have been accepted
- Continued application of an acceptable supplier/item/service performance record will include a documented periodic update and review to assure that the supplier/item/service maintains an acceptable performance record, not to exceed three years

Different forms of acceptable supplier performance data for historical performance may be compiled utilizing monitored performance of the item, industry product tests, certification to national codes and standards (non-nuclear specific), and other industry records or databases.

C.2 Commercial Grade Services

Commercial grade services must be managed to verify they perform their intended safety function. Commercial grade services may include training, calibration, testing, engineering, computer software support, and other technical support. Services may also include work on equipment or items that do not physically alter an item's critical characteristics, including installation, repair, cleaning, or maintenance.

Consider the following methods to see whether they can provide adequate acceptance of services prior to implementing commercial grade dedication methods:

- Technical verification of data produced
- Surveillance and/or audit of the activity
- Review of objective evidence for conformance to the procurement document requirements
- Performance of the service under a nuclear QA program, including Argonne's

C.3 Supplier Deficiency Corrective Action in accordance with ESQ-QA-7.1, *Supplier Corrective Action Requests*

Deficiencies identified in the supplier's processes and controls identified in the dedication process affecting CGIs must be corrected by the supplier and verified by Argonne prior to CGI acceptance.

Records

Records will be established and maintained to indicate the performance of the following functions:

- Dedication plans/ANL-746, *Commercial Grade Item Dedication Record*
- Technical evaluation of the safety function (e.g., test reports, inspection reports, analysis reports, commercial grade survey reports, source verification reports, historical performance information)
- Supplier evaluation and selection (in accordance with ESQ-QA-4.1, *Performing Supplier Evaluations)*

- Acceptance of items or services (in accordance with LMS-PROC-49, *Receipt Inspection*, or ESQ-QA-8.1, *Source Verification*).
- Supplier nonconformances to procurement document requirements, including their evaluation and disposition (and acceptance by Argonne for Use-as-is or Repair dispositions via Supplier Disposition Requests identified in the applicable ANL-407)
- Utilization and acceptance of commercial grade items

Exhibit D: CGI (Services, Work Activities, Processes) and CGD Quality Planning

When the CGD process is used to supplement a service provider's quality program, the quality planning is integrated into the provider's overall project plan. Argonne involvement may need to start in the design phase, or it may be sufficient to do only a final inspection and acceptance at the end of a project. In order to be cost effective, tailored to the need to provide verification of the work processes and end products, and to guarantee that the overall quality level is achieved, the Argonne organization(s) that provides the supplemental quality assurance program must coordinate with the service provider. In some cases, Argonne may need to generate procedures necessary to control work activities or processes.

The following items may be included in the quality plan to supplement the service provider's activities for any given application of CGD:

- Supplier's QA program documents (status and content);
- Supplier's detailed work instructions, procedures, process qualification practices, etc.;
- Supplier's design and design disclosure document generation, approval, and release documented practices;
- Supplier's configuration management documented practices;
- Supplier's self-initiated nonconformance or failure reporting documentation practice;
- Supplier's receipt inspection system and determination when Argonne will do acceptance inspection on supplier-provided hardware;
- Supplier's proposed inspection plan for Argonne approval and possibly with Argonne-injected witness or hold points;
- Definition of specific design/process change control with Argonne approval of changes;
- Definition of specific stop-work responsibilities and authorities;
- Ownership of records and rights to copies of records/documents generated over the course of the work;
- Argonne's equipment use or oversight of supplier's use of lifting, handling, and rigging equipment;
- Inspection, test, and NDE personnel qualification requirements for either the vendor or Argonne;
- Procedures for and qualification of welding, brazing, heat treatment, workmanship standards, etc.;
- Storage requirements for materials and equipment staged for installation;
- Description of measuring test and equipment (M&TE) calibration requirements, processes, and program;
- Housekeeping controls and expectations; and
- Interface with the supplier and other Argonne requirements for environment, safety, and health considerations.

Exhibit E: Requirements for Certificates of Conformance

When a Certificate of Conformance is used to support commercial grade dedication, the following requirements must be met:

a. The purchased material or equipment must be identified, such as via the purchase order.

b. The specific procurement requirements met by the purchased material or equipment (e.g., codes, standards, specifications) must be identified.

c. Any procurement requirements that have not been met must also be identified, together with an explanation and the means for resolving the nonconformances.

d. Certificate must be signed or otherwise authenticated by an individual responsible for this QA function, as described in the supplier's QA program.

e. There must be a documented certification system, as described in the supplier's or Argonne's QA program.

f. The means will be provided to verify the validity of supplier certificates and the effectiveness of the certification system (e.g., audits of the supplier, independent inspection or test of the items). Verification will be conducted at intervals commensurate with the supplier's past quality performance

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Exhibit F: Process Flowchart